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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,930	03/22/2004	Sergey Anatolievich Lukyanov	CLON-094	2888

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,930	LUKYANOV, SERGEY ANATOLIEVICH	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 17 drawn to a nucleic acid molecule, a construct comprising a vector, an expression cassette, a cell comprising an expression cassette, a kit comprising the said nucleic acid and a method of producing a polypeptide, classified in class 435, subclass 69.1.

II. Claim 11, drawn to a protein, classified in class 530, subclass 350.

III. Claim 12, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claims 13-14, drawn to a transgenic organism comprising a transgene, classified in class 800, subclass 3.

V. Claim 15, drawn to a method of detection using a fluorescent protein, classified in class 435, subclass 7.1.

VI. Claim 16, drawn to drawn to a method of detection using a nucleic acid molecule, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I.

Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acid of Invention I and the antibody of Invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

Inventions IV and (I-III) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The product of invention of Group I is a nucleic acid molecule that can be used as probe, the product of invention of Group II is a polypeptide an can be used in an assay, the product of invention of Group III is an antibody and is used in an immune response, the product of Group IV is a transgeneic animal and can be used in the production of polypeptides.

The products of inventions I, III and IV are not used in the method of invention of Group V and thus are unrelated.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as the process of DNA hybridization or PCR.

The proteins of Invention II are related to the antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in materially different process such as the process of making anti-bodies.

The products of inventions II, III and IV are not used in the method of invention of Group VI and thus are unrelated.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The method of invention of Group V is a method of detection using a fluorescent protein, the method of invention of Group VI is a method of detection using a nucleic acid molecule.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter and different search restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after

final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Mr. Bret Field on August 9, 2004 a provisional election was made with traverse to prosecute the invention of Group I, **claims 1-10 and 17**. Affirmation of this election must be made by applicant in

replying to this Office action. **Claims 11-16** are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

The current application filed on March 3, 2004 is a CIP of PCT/US02/32560, filed on October 10, 2002, which is a CIP of 09/976,673 filed October 12, 2001 and claims priority to provisional applications 60/356,225 filed February 11, 2002 and 60/383,336 filed on May 22, 2002.

Preliminary Amendment

The preliminary amendment filed June 23, 2004 has been entered.

Information Disclosure Statement

The IDS filed June 23, 2004 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding **claims 1-10 and 17**, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The nucleic acid molecule as claimed, has a sequence duplicative of that of the nucleic acid molecule encoding a polypeptide product comprising a first and second chromo/fluorescent domain or the cellular precursor thereof and possesses the biological and functional properties of the naturally occurring nucleic acid molecule encoding a polypeptide product comprising a first and second chromo/fluorescent domain and therefore does not constitute patentable subject matter absent recitation of "isolated and purified" in the preamble.
See *American Wood v. Fiber Disintegrating Co.*, 90 U. S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U. S. 1 (1931); *Funk Brothers Seed Co. v. Kalo Inoculant*, 33 U. S. 127 (1948); and *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. WO 01/32688 (Cited in the IDS filed June 23, 2004). The present invention is an expression cassette comprising a nucleic acid molecule encoding a first and second chromo or fluorescent non-bioluminescent protein from an *anthozoan* species wherein the two mentioned first and second domains are oligomeric. Ward et al. teach that a construct comprising a *Renilla* GFP sequence can be operably fused to a second sequence encoding a fluorescent protein such as *anthozoan* luciferase. Ward et al. further teach that the two encoded polypeptides may interact with each other via a protein-protein interaction and that the interaction may be detected by the resonance of energy from one fluorescent molecule to the other (page 28, lines 15-28) (**present claims 1-7**) Ward et al. also teach that the availability of nucleic acid molecules encoding the *Renilla* GFP enables the production of the protein using expression methods such as a DNA encoding a desired protein that is inserted in a plasmid vector adapted for expression in a host cell (page 20, lines 14-22) (**present claims 8-10 and 17**) . Thus Ward et al. teach all the elements of **claims 1-10 and 17** and these claims are anticipated under 35 USC 102(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-12 and 19** of copending Application No. 10757356. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose polypeptides that have identical characteristics as the claimed polypeptides of the present invention. In the specification of application 10757356 the applicants state the nucleic acid compositions encode novel chromo/fluoroproteins, wherein the proteins of interest are colored or fluorescent and this feature arises from the interaction of two or more residues of the protein. The applicants further disclose that encoded subject proteins are obtained from non-bioluminescent Anthozoans (page 2 of the specification, lines 6-14)

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-24 and 30** of copending Application No. 10006922. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose polypeptides that have identical characteristics as the claimed polypeptides of the present invention. In the specification of application 10006922 the applicants state the nucleic acid compositions encode novel chromo/fluoroproteins, wherein the proteins of interest are colored or fluorescent and this feature arises from the interaction of two or more residues of the protein. The applicants further disclose that encoded subject proteins are obtained from non-bioluminescent Anthozoans (page 2 of the specification, lines 11-25)

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBM

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